Research Article

Comparison of energy efficiency between Wearable Power-Assist Locomotor (WPAL) and two types of knee-ankle-foot orthoses with a medial single hip joint (MSH-KAFO)

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Objective: To compare the energy efficiency of Wearable Power-Assist Locomotor (WPAL) with conventional knee-ankle-foot orthoses (MSH-KAFO) such as Hip and Ankle Linked Orthosis (HALO) or Primewalk.
Study design: Cross over case-series.
Setting: Chubu Rosai Hospital, Aichi, Japan, which is affiliated with the Japan Organization of Occupational Health and Safety.
Methods: Six patients were trained with MSH-KAFO (either HALO or Primewalk) and WPAL. They underwent 6-minute walk tests with each orthosis. Energy efficiency was estimated using physiological cost index (PCI) as well as heart rate (HR) and modified Borg score. Trial energy efficiency with MSH-KAFO was compared with WPAL to assess if differences in PCI became greater between MSH-KAFO and WPAL as time goes on during the 6-minute walk. Spearman correlation coefficient of time (range: 0.5–6.0 minutes) with the difference was calculated. The same statistical procedures were repeated for HR and modified Borg score.
Results: Greater energy efficiency, representing a lower gait demand, was observed in trials with WPAL compared with MSH-KAFO (Spearman correlation coefficients for PCI, HR and modified Borg were 0.93, 0.90 and 0.97, respectively, all $P < 0.0001$).
Conclusions: WPAL is a practical and energy efficient type of robotics that may be used by patients with paraplegia.

Keywords: Wearable power-assist locomotor, Orthosis, Energy efficiency, Physiological cost index, Spinal cord injury, Rehabilitation

Introduction

The inability to walk and stand can lead to joint contractures, pressure injuries, accelerated osteoporosis, spasticity and shortened life expectancy.[1–3] To restore the gait of patients with paraplegia, different types of hip-knee-ankle-foot orthoses (HKAFOs) have been studied. Orthoses equipped with bilateral-sided hip joints and hard pelvic supports have been widely used.[4] However, these lateral system orthoses, such as hip guidance orthosis (HGO) and reciprocating gait orthosis (RGO) have an external hardware that makes it difficult for them to be used with wheelchairs.

More recently, new types of orthoses that have a medial single hip joint located inside the thigh under

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DOI 10.1080/10790268.2016.1226701

the perineum have been used. Walkabout, Primewalk and hip and ankle-linked orthosis (HALO) are commonly available to most clinical practices.[5–7] They have great standing stability, enabling the wearer to stand with their hands free when wearing the orthosis. Users can also put on and take off this type of orthosis in their wheelchairs.

However, both the lateral and medial systems are difficult to use regularly because of the high loads applied to the upper limbs.[6,8]

Gait-assisted robots for patients with paraplegia, such as ReWalk, have been shown to provide most users with the ability to independently transfer and walk.[9,10] However, it is unlikely that wearers can put them on and take them off in their wheelchairs because of the lateral system, and will likely need to use chairs.

Wearable Power-Assist Locomotor (WPAL) is expected to resolve many of the problems posed by earlier orthoses and gait-assisted robots. WPAL has a total of six motors that fit in bilateral hip, knee, and ankle joints. These motors are mounted on a frame medial to the wearer's lower limbs. Since WPAL does not have external hardware, the wearer can easily attach and remove them in their wheelchairs, and can also stand from their wheelchairs (SCI).[11] In addition to these advantages, confirming the greater energy efficiency, or lower gait demand of WPAL would also be important when assessing the practical uses for this robot. We previously indicated that gait demand of WPAL may be lower compared with MSH-KAFO from a preliminary investigation of one patient with spinal cord injury (SCI).[11] In this study we compared the energy efficiency of WPAL with HALO and Primewalk in patients with SCI.

Our primary hypothesis was that physiological cost index (PCI) during a 6-minute walk with WPAL is less than MSH-KAFO. Since PCI increases during walking in general, we tested whether the increase during walking with MSH-KAFO would be greater than with WPAL.

Materials/participants and methods

WPAL

WPAL is a motorized orthosis that consists of a wearable robotic element and a customized walker. The walker carries the batteries, motor drivers and central processing unit (CPU) that control the actuators of the robotic elements of the WPAL (Fig. 1a). The user puts on the WPAL while seated in the wheelchair (Fig. 1b). The user holds the customized walker with his/her hands and operates the switches to stand up. Parameters such as stride length, swing time and double support time can be changed to suit the wearer's gait ability using a wireless portable computer.

Patient inclusion and exclusion criteria

Six participants (two females, four males) admitted to Chubu Rosai hospital between September 2013 and January 2016 because of a SCI participated in this study (Table 1). They were characterized as scale A (five patients) and B (one patient) according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) by the American Spinal Injury Association (ASIA) related to injuries to C8-T11. Average participant age was 25.0 years (range: 19–34). The average time since injury was 6.0 months (range: 3–10).

Inclusion criteria for this study were: 1) motor complete paraplegic patients (ASIA scale A or B) with C8-L1 injuries; 2) height of 145–180 cm; and 3) weight less than 80 kg. The first requirement was because of the buttons and levers on both sides of the walker's grip, requiring participants operate them to stand or sit and to start or stop walking. Participants would also need to shift their weight from side-to-side using their upper extremities to match the WPAL's rhythm. The latter two criteria are according to the manufacturer's instructions. Exclusion criteria were: 1) progressive disease; 2) dementia or altered consciousness; 3) high risk for fractures of the lower limb or spine (severe osteoporosis); 4) severe contracture of the limbs or spine; 5) pressure injuries at points of contact with the orthosis; 6) uncontrolled high blood pressure (more than 180 mmHg systolic blood pressure or more than 120 mmHg diastolic blood pressure at rest); 7) uncontrolled tachycardia (ventricular rate of at least 120 beats per minute); and 8) limited exercise because of disturbed cardiac or respiratory function (to the point where wheelchair operation causes shortness of breath).

Training schedule

Before patients started to walk with WPAL, they were trained to walk with one of two types of conventional orthoses (HALO or Primewalk). HALO has a linking mechanism that connects both ankle joints with a medial hip joint (Fig. 1c). The system allows wearers to keep both feet parallel to the floor while walking, and assists with leg swing when the contralateral ankle is flexed dorsally during loading.[7] In contrast, Primewalk has a sliding hip joint, which allows the imaginary axis of the hip joint to be positioned 60 mm

Figure 1 Upper left panel (a): WPAL consists of a wearable robotic orthosis and a custom walker. The walker carries the batteries, motor drivers and central processing unit that control the actuators of the robotic parts of WPAL Upper right panel (b): The user dons the WPAL while seated in the wheelchair. Lower left panel (c): HALO has a linking mechanism that connects each ankle joints with a medial hip joint. This enables users to keep their feet parallel with the floor. Lower right panel (d): Primewalk has a sliding hip joint, which allows the imaginary axis of the hip joint to be positioned 60 mm above the real joint.

above the real joint (Fig. 1d). The imaginary axis of the hip joint of Primewalk is closer to the natural hip joint than the design of the Walkabout.[6]

After their being trained to walk independently with either a HALO or Primewalk orthosis using a walker, a gait training program with WPAL was started. Patients

Table 1 Study participant characteristics.

Participant	Sex	Age (years)	Height (cm)	Weight (kg)	Neurologic level of injury	ASIA Scale	Type of MSH-KAFO	Time since injury (months)
1	Female	34	164	42	T10	A	HALO	10
2	Male	23	169	49	T11	A	HALO	5
3	Male	19	174	70	T8	A	HALO	9
4	Male	22	175	63	C8	B	HALO	5
5	Male	26	172	57	T9	A	Primewalk	4
6	Female	26	157	38	T11	A	Primewalk	3

MSH-KAFO indicates knee-ankle-foot orthoses with a medial single hip joint; ASIA, American Spinal Injury Association; HALO, hip and ankle linked orthosis.

first attempted a stepping exercise using parallel bars suspended with a harness. The harness is not for partial body weight support but for fall prevention. Patients learned to shift their weight from side to side to create a rhythm. Patients then begin gait exercise with parallel bars, followed by attempted gait with a walker. Patients remained on the third stage until they could walk safely and independently with a walker (Fig. 2). They were then permitted to walk with the walker without suspension. Device parameters were changed using a wireless portable computer depending on the user's gait ability. The present study used the following parameter ranges: stride length (0–60 cm), swing time (0.9–1.0 sec) and double support time (0.05–0.5 sec).

Participants were trained with MSH-KAFO for 30 to 60 minutes per session and 3 to 5 sessions per week for 1 to 3 months until they could walk independently with the device. They were then advanced to walking with WPAL for 30 to 60 minutes per session, 1 to 5 sessions

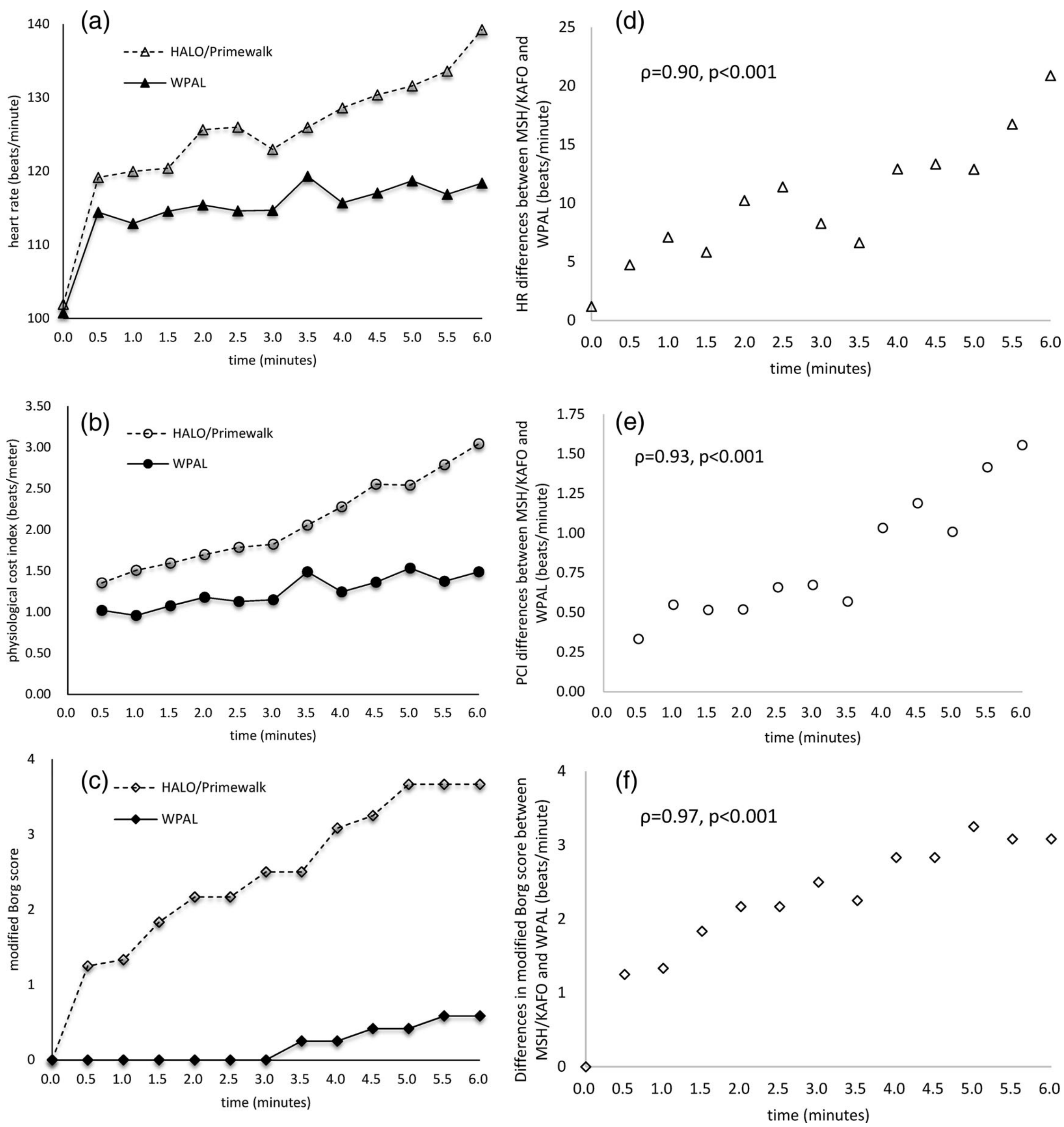

Figure 2 Upper left panel (a): Change in heart rate (beats/minute) in MSH-KAFO (HALO or Primewalk) and WPAL. Middle left panel (b): Change in physiological cost index (beats/meter) in MSH-KAFO (HALO or Primewalk) and WPAL. Lower left panel (c): Change in modified Borg score in MSH-KAFO (HALO or Primewalk) and WPAL. Upper right panel (d): Spearman correlation coefficients for heart rate (beats/minute) in MSH-KAFO (HALO or Primewalk) and WPAL. Middle right panel (e): Spearman correlation coefficients for physiological cost index (PCI, beats/meter) in MSH-KAFO (HALO or Primewalk) and WPAL. Lower right panel (f): Spearman correlation coefficients for modified Borg score in MSH-KAFO (HALO or Primewalk) and WPAL.

per week for 1 to 3 months. Participants continued with MSH-KAFO training while they learned to walk with WPAL. Participants were therefore trained with MSH-KAFO for approximately double the amount of time that they were exposed to WPAL.

Statement of ethics

Written informed consent was obtained from all participants. This study was approved by the institutional ethics committees of Fujita Health University (No.13–204), and the Japan Organization of Occupational Health and Safety Chubu Rosai Hospital (201308–02).

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this study.

Comparing energy efficiency between WPAL and MSH-KAFO

Participants underwent a 6-minute walk test with MSH-KAFO (either HALO or Primewalk) and WPAL. When they walked with MSH-KAFO, they were instructed to do so with as consistent a speed as possible. To assess energy efficiency, we used the PCI proposed by MacGregor.[12] PCI is calculated by dividing the difference in heart rate (HR) during walking and rest by walking speed. PCI has been reported as an outcome measure for patients with SCI,[8, 13–16] as HR has been known to have a significant positive correlation with oxygen uptake in patients with SCI.[17] HR was recorded every 30 seconds using a portable HR monitor and a Holter electrocardiograph. Gait velocity was calculated by measuring the distance ambulated during every 30-sec interval. We set the WPAL parameters to match the same walking speed as MSH-KAFO. The modified Borg scale was also assessed every 30 seconds to evaluate perceived exertion.[18]

Patients also underwent consecutive walking challenges with MSH-KAFO and WPAL (Table 2). They walked continuously at a comfortable speed with each MSH-KAFO and WPAL until they felt fatigue.

Statistical analyses

We first calculated PCI differences between MSH-KAFO and WPAL at each time point (0.5–6.0 minutes). We then examined whether this difference increased over time. More specifically, the average PCI of the six patients was calculated for MSH-KAFO and WPAL separately at each time point. Differences between MSH-KAFO and WPAL calculated for each time point were assessed for Spearman correlation coefficient with time (range: 0.5–6.0 minutes). The same procedure was repeated for HR and modified Borg score. Comparisons of consecutive walking times and distances were performed with the Friedman test. All statistical analyses were performed with SPSS version 23.0 (IBM Corp., Armonk, NY, USA).

Results

During the 6-minute walk, gait demand increased more with MSH-KAFO than with WPAL. The difference in PCI between MSH-KAFO and WPAL became significantly greater over time (Spearman correlation coefficient $\rho = 0.93$ and $P < 0.0001$, Figs. 2b and 2e). Similarly, HR and modified Borg score during the 6-minute walk with MSH-KAFO were significantly greater than with WPAL (Spearman correlation coefficients 0.90 and 0.97, respectively; both $P < 0.0001$, Figs. 2a, 2c, 2d and 2f).

Time and distance achieved in consecutive walking challenges were both greater with WPAL than with MSH-KAFO (Friedman test $P = 0.025$ and $P = 0.014$, respectively) (Table 2). Two participants (numbers 1 and 2) continued walking with WPAL until the battery ran out.

Table 3 shows qualitative findings regarding differences between WPAL and MSH-KAFO. All participants subjectively enjoyed walking with WPAL more than MSH-KAFO. Three commented that walking with WPAL more closely resembles normal gait, using their phrase “I feel natural bodily vertical movement during walk.”

Discussion

In the present study, we showed significantly greater energy efficiency of WPAL compared with MSH-KAFO, consistent with our preliminary investigations.[11,13]

When patients with SCI walk using conventional orthoses, they must maintain balance during gait and transfer using their upper extremities.[6] Since they cannot create sufficient clearance during the swing phase, they need to bend their trunks towards their standing leg, which could be a reason for their high gait demand (low energy efficiency) while ambulating with MSH-KAFO.

When patients walk with WPAL, the functional length of the leg can be shortened during the swing phase because the hip and knee are flexed by power sources. That is why WPAL has sufficient toe clearance during the swing phase. This permits WPAL wearers to walk only with a moderate amount of lateral weight shift, without using more upper extremity energy.[13]

The aforementioned functional differences between WPAL and MSH-KAFO would be reasonable explanations for the improved gait and lower energy

Table 2 Comparing the time and distance of consecutive walking challenges between MSH-KAFO and WPAL.

	HALO or Primewalk		WPAL	
Participant	Time (minutes)	Distance (meters)	Time (minutes)*	Distance (meters)†
1	60	700	84	1513
2	28	700	54	983
3	10	70	24	252
4	30	200	31	373
5	9	70	9	124
6	8	60	24	277

MSH-KAFO indicates knee-ankle-foot orthoses with a medial single hip joint; WPAL, wearable power-assist locomotor; HALO, hip and ankle linked orthosis.
*Walking time is significantly greater with WPAL than with MSH-KAFO (HALO or Primewalk) ($P = 0.025$ by Friedman test), †Walking distance is significantly greater with WPAL than with MSH-KAFO (HALO or Primewalk) ($P = 0.014$ by Friedman test).

demand of WPAL compared with MSH-KAFO. In our study, PCI, HR and modified Borg score increased significantly more during the 6-minute walk with MSH-KAFO than WPAL. This finding suggests that participants could walk longer without requiring more energy when wearing WPAL. In the consecutive walking challenge, two participants (number 1 and 2) actually continued walking until the battery ran out. Even after their longest walk, they did not complain of fatigue. It was speculated that they could have walked much longer with a larger battery.

Indeed, walking with MSH-KAFO would have required higher static (isometric) upper extremity effort than walking with WPAL, as the participants had to hold their trunk with their upper extremities applying force to shift weight. Walking load on the upper extremities was previously reported to be higher when walking with Primewalk than WPAL, based on the higher percentage of maximum voluntary contraction (%MVC) measured using surface electromyography (EMG).[13]

Spearman correlation coefficients for modified Borg score were 0.97, which seemed higher than that for HR (0.90). We speculate that HR increase was relatively modest in MSH-KAFO trials in spite of the experienced exhaustion. For increases in oxygen consumption, cardiac output and HR are generally modest during static exercise compared with dynamic exercise[19] because of the peripheral vasoconstriction.[20,21] Reduced blood supply and higher metabolic demands could cause anaerobic dominant metabolism, leading to a more rapid fatigue onset.[19]

Table 3 Qualitative feedback regarding MSH-KAFO and WPAL use.

MSH-KAFO (HALO or Primewalk)	
	I felt as if each of my legs had been a straight stick and leg movement during gait was like swinging the stick.
	I felt my legs becoming warm but not as much as WPAL.
	I got short of breath at the slower speed when walking with MSH-KAFO than with WPAL.
WPAL	
	Walking with WPAL resembles a more normal gait, that is, I feel natural body vertical movement when walking.
	I felt my legs becoming warm gradually from my toes up to the thigh when walking.
	I felt warm and sweaty on my face, back, and thighs, but I was not short of breath and I keep relaxed when walking.

MSH-KAFO indicates knee-ankle-foot orthoses with a medial single hip joint; WPAL, wearable power-assist locomotor; HALO, hip and ankle linked orthosis.

Some might argue that the longer training session duration of WPAL training compared with MSH-KAFO resulted in the differences observed in this study. However, participants actually trained with WPAL for less time overall than MSH-KAFO. They practiced with MSH-KAFO for 1–3 months, then started WPAL training while continuing to walk with MSH-KAFO for approximately the same duration.

Besides the low energy cost, there is another advantage of WPAL. Walking with WPAL resembles natural gait. The knee joint flexes slightly to load the wearer's body weight on the whole foot during initial contact. As the knee extends and the ankle dorsiflexes in mid-stance, the wearer's body mass moves forward and center of gravity moves upward. Vertical body movement during walking is an essential component of normal gait.

Safe use is also a very important issue. First, the wearer was suspended with the harness to prevent falls until they can walk safely. Second, one person stayed behind him/her at all times since falling over backward was reported to occur most commonly during gait with WPAL.[22] Third, the training emphasized well-timed forward movement of the walker essential to avoiding falls due to unexpected postural changes. No falls were reported during the course of this study, nor were there complications such as pressure sores, cardiovascular stresses, pain or musculoskeletal problems.

There are several limitations of this study. The small number of participants may preclude any definitive conclusions. However, with only six participants we were able to show statistically significant differences in energy efficiency between MSH-KAFO and WPAL. The short battery life of the orthosis might limit the practical use of the WPAL for community ambulation. The manufacturer is now working to improve the battery. Finally, although clinical evaluation of perceived exertion, PCI and HR are good indicators of energy cost, performing a true physiologic assessment of metabolic cost may validate our results further. Mooney LM *et al.*[23] reported that the autonomous exoskeleton significantly reduced the metabolic rate calculated from oxygen consumption and carbon dioxide production measured using a portable pulmonary gas exchange device. This assessment may be performed in the future.

Conclusion

PCI, HR and modified Borg score increased significantly more during a 6-minute walk with MSH-KAFO than with WPAL. WPAL participants can therefore walk longer without requiring more energy.

Acknowledgements

We gratefully acknowledge Mr. Hagemu Higuchi and Mr. Hiroshi Deguchi of ASKA Corporation for their technical assistance. We also thank all participants for joining our study.

Disclaimer statements

Contributors None.

Funding None.

Conflict of interest WPAL used for the present study was lent free of charge from the Tomei Brace Company. AU is a salaried employee of the Tomei Brace Company. The remaining authors declare no conflict of interest.

Ethics approval None.

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